6248.200-US US Patent Application No. 10/068,224 Page 9 of 11

**2**014/027

## REMARKS

As a general matter, Applicants wish to thank Examiner Foster for the conscientious review of the applications and for providing helpful suggestions for moving this case towards allowance.

## Period for Response

As reported to Examiner Foster by the undersigned on July 28, 2004, the Office Action mailed February 18, 2004 was never received by Applicants. PAIR records indicate that the Office Action was apparently returned to the Office on March 3, 2003 and apparently no further action was taken by the Office concerning it.

A formal customer number request was previously made in connection with this patent application prior to the mailing of the February 18, 2004 Office Action and, in accordance with the Office's instructions to Applicants' representative, Applicants' representative's customer number and request to use the same was also included in the most recently filed Amendment (Novo Nordisk® Pharmaceuticals has been instructed by the USPTO to make such an indication in all of our papers due to the repeated failure of the USPTO to use our correct address with any consistency). The fact that the Office Action was mailed and never received was only recently discovered during a regular (unspecific) review of applications associated with representative's customer number in Private PAIR on about July 22, 2004. Novo Nordisk Pharmaceuticals has had numerous cases mishandled in this matter and in all such cases to date the USPTO has reset the period for response.

In this respect, and at Examiner Foster's request, a Petition to the TC Director under 37 CFR 1.181 and in accordance with MPEP § 710.06 and 1160 OG 14, requesting resetting of the period for response to the February 18, 2004 Office Action, is submitted concurrently herewith (a copy is enclosed herewith).

## Claim Amendments

Claims 5-6, 8-20, and 23-36 are amended to clarify the claim elements and thereby obviate the issues raised in the Office Action. The majority of these amendments are to the form of the claim, rather than the substance, and they do not narrow the scope of these claim elements or

6248,200-US US Patent Application No. 10/068,224 Page 10 of 11

represent any sort of surrender of the scope of the claimed subject matter. New independent claim 43 and new claims 44-45, which depend thereon, are directed to preparing an aqueous solution comprising a meiosis activating substance and claims 31-36, which appear to be more amenable to methods, are amended to be dependent on new claim 43. Claim 30 is amended so as to present an independent claim, which is free of some of the elements of claim 5. These claims and amendments find support in, e.g., the original claims and Examples 3, 4, and 6. The other claim amendments also are fully supported by the specification and original claims. No new matter is added. Claims 1, 3-6, and 8-45 are pending.

## The Office Action

The Office Action rejected claims 5-20 and 23-26 under 35 U.S.C. § 112, first paragraph, as allegedly encompassing subject matter that is not adequately supported by the description and under 35 U.S.C. § 112, second paragraph, for being allegedly indefinite. Both rejections relate to the way that the term "atmosphere" is applied in claim 5 and the use of the term "composition" to describe various claim elements in claim 5 and claims dependent thereon. Specific rejections were raised under Section 112 concerning particular language in claims 26 and 29 that are obviated by the amendments to these claims, which removes the phrases that were the basis of these rejections. These also are clarifying amendments and do not serve to narrow the scope of these claims.

As indicated above, for clarity's sake, claim 5 has been amended such that it is directed to a "product" that comprises a container and a "pharmaceutical composition" contained in a low oxygen atmosphere in the container. The implication of the relationship between the atmosphere and the container is clear (i.e., the container contains the pharmaceutical composition in a low oxygen content atmosphere as specified in the claims). The pharmaceutical composition comprises a "meiosis activating substance" and an additive. Thus, claim 5 only uses the term "composition" to refer to a single claim element (the "pharmaceutical composition"), obviating any confusion that may have arisen from the previously proposed claim language. Claim 31, which has been made independent by this amendment, uses a similar set of claim elements. It is believed that the new claim language addresses the issues raised in the Office Action under Section 112.

6248.200-US US Patent Application No. 10/068,224 Page 11 of 11

In view of the claim amendments and remarks made herein, it is respectfully submitted that all of the pending claims are in condition for allowance. Early action to that end is respectfully requested. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner is invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Date: August 4, 2004

Len S. Smith, Reg. No. 43,139 Novo Nordisk Pharmaceuticals, Inc.

100 College Road West Princeton, NJ 08540 (609) 987-5800

Respectfully submitted,

Use the following customer number for all correspondence regarding this application.

PATENT TRADEMARK OFFICE